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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,661	04/16/2004	Peter K.T. Pang	2968-150	8482

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,661	PANG ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/30/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-35* is/are pending in the application.

4a) Of the above claim(s) *26-30 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-25 and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 21-35 are pending.

2. Response to restriction requirement filed 01/30/2006 is acknowledged. Applicant elected, with traverse, Group I, claims 21-23,25,31-34 drawn to a shark cartilage extract and method of making of the same. Applicant requests rejoining claim 24 with Group I. Claim 24 is added to the claims under examination. Claims 26-30,35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 24,26-30,35 is requested.

Priority

3. The parent application 09/462094 was closely reviewed. It is noted that the parent application does not disclose shark cartilage extract prepared as now claimed (see written description rejections below). Correspondingly, the instant claims are not entitled to the effective filing date of the parent application.

In addition, the claim for priority under 35 U.S.C. 120 is objected to because it is not the first sentence of the specification. See 37 CFR 1.78(a)(2).

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 21-25, 31-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 21-25, 31-34 presented in this application address limitations that have not been disclosed in the specification as filed.

A. First, the claims recite now that extraction of shark cartilage, as well as second extraction of pellet is carried out at temperature range 85°-120° C for 2-4 hours. Neither the range of 85°-120° C, nor extracting at this temperature range for from 2 to 4 hours is not disclosed in the specification. Example 1(p.8) teaches extracting 85° C for 2 hours.

B. Second, with respect to claims 21-25, specification does not disclose lyophilizing the pooled extract. Contrary, specification teaches spray drying. See Example 1.

5. Claims 21-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to shark cartilage extract and method of making thereof. The functional limitation of the extract is anti-parathyroid hypertensive factor activity of the extract. However, specification does not disclose extract which is being lyophilized at the last step. Note, that Dupont et al (US 5618925) attempted to lyophilize liquid shark extract but discovered that this results in loss of its biological activity (see col. 8, lines 45-48), col. 10, lines 65-67, col. 11, lines 30-35). The instant specification neither presents working example demonstrating obtaining extract having biological activity as claimed, nor provides guidance on how achieve such effect with extract made as claimed.

The skilled practitioner would first turn to the instant specification for guidance in practicing the claimed method, however the specification only provides guidance to extract obtained by spray drying. As such the practitioner would turn to the prior art for such guidance, however the prior art teaches that such step might result in a loss of biological activity. Finally, said practitioner would turn to trial and error experimentation which represents undue experimentation.

Claim Rejections - 35 USC § 102 and 103.

6. Claims 21-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Dupont et al (US Patent 5,618,925). Claims 21-25 are in product-by-process format and is are drawn to a shark cartilage extract prepared by extraction shark cartilage at 85-120^{0}C for 2-4 hours, cooling the extract and separating supernatant from pellet by centrifugation. This supernatant

(supernatant 1) is combined with the supernatant 2 obtained by the repeated extraction with water of the pellet remaining after supernatant 1 separation.

Dupont et al teach shark cartilage extract. See summary and claim 1. The reference teaches that methods of obtaining shark cartilage extracts are well known. Among other methods, known methods include aqueous extractions in water or salt solutions and elimination of unsolubilized material. See column 2, lines 30-45. Further, the patent describes preparation of shark cartilage extract by extraction by water, and separation of unsolubilized material by centrifugation. Many other aqueous solutions can be used in lieu of water. See col. 4, last two paragraphs. The composition of the supernatant is disclosed in the table, column 5. Several different fractions of supernatant can be further separated, as disclosed in columns 10,11. The resulting supernatant cam be lyophilized (col. 7), although such step may result in a loss hypoplasiant activity – see, e.g. col. 11, lines 30-35 - although cell growth arresting activity remains (col. 7). Claims 21-25 are in product-by-process format, and as such, it is the novelty and patentability of the instantly claimed product that need to be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, USPQ (CCPA 1976). Therefore, as Dupont et al teach shark cartilage extract, the reference anticipates the instantly claimed product. Since the Office does not have the facilities for examining and comparing applicants' extract with the extract disclosed in the prior art, the burden is on applicant to show novel or unobvious difference between the claimed product and the product of the prior art. See

In re Best, 562 F.d. 1252, 195 USPQ 430 (CCPA 1977) and *In re* Fitzgerald et al., 205 USPQ 594.

As for the claimed anti-PTH activity of the extract, it has been held that where applicant claims a composition in terms of function, property or characteristic where said function is not explicitly shown by the reference and where the examiner has explained why the function, property or characteristic is considered inherent in the prior art, it is appropriate for the examiner to make a rejection under both the applicable section of 35 USC 102 and 35 USC 103 such that the burden is placed upon the applicant to provide clear evidence that the respective compositions do in fact differ. Since the Office does not have the facilities for examining and comparing applicants' extract with the extract disclosed in the prior art, the burden is on applicant to show novel or unobvious difference between the claimed product and the product of the prior art. See *In re* Best, 562 F.d. 1252, 195 USPQ 430 (CCPA 1977) and *In re* Fitzgerald et al., 205 USPQ 594.

In regard to claim 25 providing percentile content of the components in the extract, the reference either merely acknowledges the presence of a component (in regard to mucopolysaccharides; col. 5, line 60) or presents the content of the supernatant in a manner different from those used in the instant claims (in regard to protein, col. 5, line 41). Again, since the Office does not have the facilities for examining and comparing applicants' extract with the extract disclosed in the prior art, the burden is on applicant to show novel or unobvious difference between the claimed product and

the product of the prior art. Further, it would be a matter of routine experimentation to select optimal concentration ranges of components of a cartilage composition.

In regard to claim 24, the anti-angiogenesis agents of the reference can be used in anti-cancer cocktail comprising anti-angiogenesis agent and supplementary potentiating agents, such as antihypertensive agents and Ca antagonists (the latter also being anti-hypertensive agents). See col. 5, lines 1-5, 30-43.

Prior art made of record

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 3,371,012 teaches a shark cartilage extract prepared cartilage extraction with aqueous solution at 70°C for 3 hours and filtration of the extract through a "Celite" column. See col. 3, lines 20-31.

US 4,473,551 teaches a shark cartilage extract prepared by extraction of shark cartilage with water at temperature 0-50°C for 4-24 hours. The extraction procedure include repetitive extraction of the same portion of cartilage with new portions of water, to increase extraction of active components. See col. 2, lines 35-55.

US Patents 5985839, 6025118 and 6025334 are other patents of Dupont et al, all describing shark cartilage extracts and methods of their preparation.

Conclusion.

8. No claims are allowed

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631